IFW B



Dkt. 43016-A-PCT-US/JPW/JW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Philip O. Livingston and Friedhelm Helling

Serial No.: 08/196,154 Examiner: A. Holleran

Filed: November 16, 1995 Group Art Unit: 1642

For : GANGLIOSIDE-KLH CONJUGATE VACCINES PLUS

QS-21

1185 Avenue of the Americas New York, New York 10036

September 28, 2005

MAIL STOP ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

AMENDMENT PURSUANT TO 37 C.F.R. §1.312

This Amendment is submitted pursuant to 37 C.F.R. §1.312. According to 37 C.F.R. §1.312, an Amendment after a Notice of Allowance must be filed before or with the payment of the issue fee. Applicants are concurrently paying the issue fee. Accordingly, this Amendment is being timely filed.

Please amend the subject application as follows:

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Amendments to the Brief Description of the Figures

Please replace the paragraph beginning at page 5, line 4, with the following amended paragraph:

Figure 1A-1B

1A and 1B: The synthesis of GD3 protein conjugates after ozone cleavage and reductive amination.

Insert represents HPTLC of GD3 before (lane A) and after (lane B) the cleavage.

Please replace the paragraph beginning at page 6, line 11, with the following amended paragraph:

Figures 8A-1 and 8A-2 8A - 8B

8A and 8B: Specificity of peak titer sera from patients immunized GM2-KLH + QS-21 vaccine determined by immune layer chromatography as described previously (3, Reference of the Third Series of Experiments). melanoma GM2 (A) and ganglioside extract (B) were applied to TLC plates, incubated with sera from individual patients and stained with peroxidase-labeled goat antihuman IgM or IgG antibody. MAb 696 was used as positive control for GM2 and resorcinol stain for gangliosides.

Please replace the paragraph beginning at page 6, line

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24, with the following amended paragraph:

Figure 8B 8C

Inhibition of IgG reactivity of patient serum against GM2 and GD2. GM2 (A) and melanoma tissue ganglioside extract (B) were applied plates, incubated with HPTLC serum from patient No. 2 and stained with peroxidase-labeled goat anti-IgG antibody. 3ml Patient human serum at a dilution of 1:50 was preincubated with either 150µg GM2 GD2 prior to 150µg staining.

Please replace the paragraph beginning at page 6, line 33, with the following amended paragraph:

Figures 9A, and 9B, 9C, and 9D

IgM and IgG antibody response in melanoma patients after immunization with GM2-KLH plus QS-21 vaccines. Sequential results for six patients receiving the 100 ug QS-21 dose are shown in Figures 9A and 9B Figure 9a and for six patients receiving the 200 ug dose in Figures 9C and 9D Figure 9b. Note that one patient in group received only four each vaccinations and was taken off study due to disease progression. Arrows indicate the time of GM2-KLH cyclophosphamide (Cy) and plus QS-21 vaccine injections.